

REMARKS

Favorable reconsideration of this application, as presently amended and in light of the following discussion, is respectfully requested.

After entry of the foregoing amendment, Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 are pending in the present application. No new matter has been added.

By way of summary, the Official Action presents the following issues: Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 stand rejected under 35 U.S.C. §112, first paragraph; and Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 stand rejected under 35 U.S.C. §103 as being unpatentable over Yu, et al. (U.S. Patent Publication 2003-0105496, hereinafter Yu).

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The Official Action has rejected Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 under 35 U.S.C. §112, first paragraph. Applicant respectfully traverses the rejection.

At paragraph 2 of the Official Action, it is noted that the limitation “only” is not supported by the specification. In citing this deficiency the Office takes the position that “any negative limitation or exclusionary proviso must have basis in the original disclosure.”

In this regard, Applicant respectfully directs the Examiner’s attention to paragraph 57 of the Applicant’s disclosure, which states “More recently, it has been found that pacing only in the left ventricle can produce beneficial hemodynamic results in some circumstances.” Therefore, the Applicant’s specification clearly describes the benefits of pacing of only the left ventricle and explains how this pacing is established through additional reference to Figure 4.

Accordingly, Applicant respectfully requests that the rejection of Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 under 35 U.S.C. §112, first paragraph, be withdrawn.

REJECTION UNDER 35 U.S.C. §103

The Official Action has rejected Claims 1, 3, 20, 27, 28, 34, 67 and 69-71, under 35 U.S.C. §103 as being unpatentable over Yu.

The Office contends that although Yu does not describe all of the features of the Applicant's claims, any deficient features are nonetheless obvious to one of ordinary skill in the art. Applicant respectfully traverses the rejection.

Applicant's Claim 1 recites, *inter alia*, a method of configuring signaling locations within a heart for performing intrachamber resynchronization, including:

positioning signaling electrodes to deliver stimulation to only a left ventricle of the heart, the signaling electrodes being positioned along a first and second axis interior to the heart, the second axis extending within the left ventricle to position at least one first signaling electrode of the signaling electrodes thereabout, the first axis extending into a right ventricular septum of the heart to position at least one second signaling electrode of the signaling electrodes at a position for delivering stimulation to the left ventricle; and

delivering, to the left ventricle, stimulation via the at least one first and second signaling electrodes for performing the intrachamber resynchronization.
(emphasis added)

As previously pointed out, Yu describes delivering multiple accelerometers internal to a heart, across multiple locations within the right ventricle and the left ventricle of the heart, Yu cannot be said to disclose or suggest Applicant's claimed configuration which delivers stimulation **to only the left ventricle of the heart via the claimed configuration of signaling electrodes**. The Office has noted that although Yu does not specifically disclose or suggest pacing only a left ventricle, that Yu nevertheless suggests such an arrangement. In this regard, the Office notes that:

... Yu discloses the essential features of the claimed invention except for explicitly disclosing that the septal electrode 144 delivers stimulation to only the left ventricle. However, it is well known in the pacing arts to provide

septal electrodes with screw-in tips that provide stimulation to only the left ventricle to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications. Therefore, it would have been obvious to one having ordinary skill in the art to provide Yu's invention with a septal electrode provides stimulation to only the left ventricle to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications.

As noted next in the declaration of inventor Dr. Morton Mower, Yu does not disclose or suggest any means by which intrachamber resynchronization is to be performed. Likewise, the rationale presented by the Office in support of the obviousness determination is misguided.

DECLARATION OF DR. MORTON MOWER, M.D.

The declaration of Dr. Morton Mower, M.D. (Exhibit A), attached herewith, makes clear that the application of the Yu reference in rejecting the current claims is improper. As such, Applicant submits that the declaration provided herewith under 37 C.F.R. §1.132 constitutes factual evidence as to the patentability of the amended claims.

The most straightforward method of pacing the left ventricle consists of pacing through a retrograde catheter placed within the left ventricle. In such a system, thrombosis complications will exist regardless of lead placement. Pacing for the right ventricle is universally believed to reduce LV delay and Left Bundle Branch Block (LBBB). When a physician sees a different pattern such as Right Bundle Branch Block (RBBB) with RV pacing, the first thought is that the pacing tip has perforated, rather than having a desired specific chamber effect as currently claimed with reference to the left ventricle.

In understanding the claimed pacing arrangement of the left ventricle, it is noteworthy that the septum separating the left and right ventricles consists of a mixture of left and right ventricular endocardium. The ratio varies in the various parts of the septum, and when the

septum is paced, it most often results in a delay in left ventricular activation. Other pulses there are sometimes conducted to the left side in a very expeditious manner, often resulting in unusual patterns of conduction in the electrocardiogram. See Mower MM, Aranaga CE, and Tabatznik B: Unusual Patterns of Conduction Produced by Pacemaker Stimuli. Amer. Heart J 74:24-28, 1967. It has never been widely appreciated that in the mid-septum the right ventricular endocardium is particularly thin, and the surface of the right side of the septum is functionally left ventricle. Thus a pacing lead placed at the exact middle of the interventricular septum on the right side can of times preferentially stimulate left ventricular myocardium without immediately affecting the right ventricle.

As can be appreciated, as Yu does not disclose or suggest by which intrachamber resynchronization is to be performed, nor does it describe or suggest any benefit of providing pacing pulses to a left ventricle via a right ventricular septum in combination with a further stimulation of the left ventricle, Yu cannot be said to render current Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 obvious under 35 U.S.C. §103.

Accordingly, Applicant respectfully requests that the rejection of claims be withdrawn.

CONCLUSION

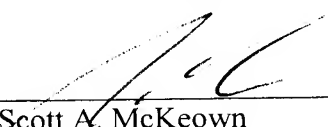
Consequently, in view of the foregoing amendment and remarks, it is respectfully submitted that the present application, including Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 is patentably distinguished over the prior art, in condition for allowance, and such action is respectfully requested at an early date.

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Respectfully submitted,
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